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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,465	04/25/2000	David Scott Dunlop	7546M	8865
27752	7590	12/07/2004	EXAMINER	
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/558,465	DUNLOP ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

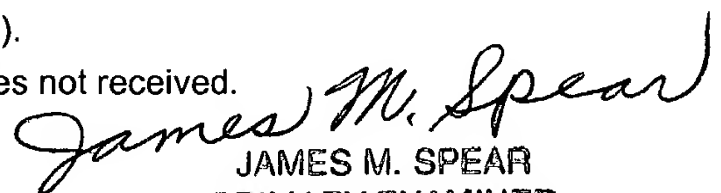
Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114, the Declaration under 37 CFR §1.132, request for extension of time (3 months-granted) and Applicant's Arguments/Remarks, all filed 07/23/04 is acknowledged.

Claims 1-9 and 11-34 are pending. No amendments to the claims have been made. Claim 10 has previously been cancelled. Claims 1-9 and 11-34 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 11-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramachandran *et al.* (WO 96/29983) in view of Cardin *et al.* (US Pat. No. 5,104,645).

Ramachandran *et al.* teach mild aqueous detergent, e.g. shampoo compositions, comprising anionic surfactants. Ramachandran teach in claim 1, "a mild aqueous detergent composition...comprising: (a) from about 4 to about 12% by weight of an anionic surfactant; (c) about 0.3 to 7% by weight of a long-chain alcohol or ethoxylated alcohol averaging about 26 to 40 carbon atoms as a suspending and conditioning agent; (d) an effective amount of a therapeutic agent selected from the group consisting of ...(ketoconazole), ...zinc pyrithione, ...coal tar, ...and mixtures thereof; and (e) about 50 to 85% by weight of water." Ramachandran *et al.* claim in claim 10 that the composition further contains a hair conditioning agent "selected from the group consisting of organosilicone compounds, aminosilicones, water insoluble hydrocarbons, ...and mixtures thereof, present at a level of from about 0.2 to 5% by weight." Ramachandran *et al.* teach at page 10, lines 4-32, specific hair conditioning agents, including guar hydroxypropyl trimethylammonium chloride.

Ramachandran *et al.* do not explicitly teach the bioavailability/coverage index, the conditioning index value, or the minimal inhibitory concentration index value of the composition. No criticality is established in the instant recitations of the various index values, since one of ordinary skill in the art could readily determine suitable index values through routine or manipulative experimentation to obtain the best possible results, as these are viewed as variable parameters. Moreover, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating

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such concentration is critical. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the instant case, Applicants have not demonstrated any criticality in the claimed index limits. The prior art teaches shampoo compositions which essentially contain the same ingredients, used for the same field of endeavor and applied in similar amounts as those claimed by Applicant. Thus, since, in essence, the shampoo composition of Ramachandran *et al.* is quite similar to that being claimed, it would be expected that the shampoo composition of Ramachandran *et al.* would also impart similar properties attainable through the employment of those same ingredients.

Regarding the molecular weight of the guar derivatives and the charge densities of the cellulose derivatives, it is the position of the Examiner, that one of ordinary skill in the art would be capable of determining suitable molecular weights and charge densities through routine experimentation, based on the intended purpose, to obtain the most optimal results.

Ramachandran *et al.* do not teach that the zinc salt of 1-hydroxy-2-pyridinethione is in platelet particle form.

Cardin *et al.* teach antidandruff shampoos comprising an anti-dandruff active being 1-hydroxy-2-pyridinethione salt in platelet particle form having an average particle size from 2 μm to about 15 μm (col. 5, lines 54-58). Cardin *et al.* teach that it is preferential to use approximately 0.3% to about 2% of the pyridinethione metal salt (col. 5, lines 58-60). Cardin *et al.* teach that the preferred salt is zinc (col. 6, lines 24-25). Cardin *et al.* teach that the synergizers include polyethylene glycols. Cardin *et al.* also teach that when the platelet form of

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a pyridinethione metal salt with a specified particle size is combined with any of a group of specific synergizers in a shampoo matrix that an unexpected substantial improvement in anti-dandruff efficacy is realized (col. 1, lines 37-45).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the anti-dandruff of Cardin *et al.* within the teachings of Ramachandran *et al.* because Cardin *et al.* teach antidandruff shampoos comprising 1-hydroxy-2-pyridinethione salt in platelet particle form having a specified particle size and similarly, Ramachandran *et al.* teach shampoo compositions comprising therapeutic agents, such as antidandruff agents (i.e., ketoconazole, zinc pyrithione, coal tar) in the shampoo compositions. The expected result would be an effective antidandruff composition that exhibits increased efficacy.

Response to Arguments

Applicant's arguments filed 07/23/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. 103(a) rejection of claims 1-9 and 11-34 over Ramachandran *et al.* (WO 96/29983) in view of Cardin *et al.* (US 5,104,645) stating, "Ramachandran does not teach that the zinc salt of 1-hydroxy-2-pyridinethione in platelet particle form and does not disclose the combination of a cationic polymer with a non-volatile

conditioning agent. The cationic agents are listed as one of many possible ingredients in the final shampoo composition and are not included in any of the specific examples.”

These arguments have been fully considered but were not found to be persuasive. Ramachandran et al. are relied upon for all that they teach as delineated above. Ramachandran et al. do not explicitly teach the zinc salt of 1-hydroxy-2-pyridinethione in platelet particle form. Cardin et al. was relied upon to remedy this deficiency of Ramachandran et al. by teaching that it is well-known in the art to employ salts of zinc pyridinethione in platelet forms, in anti-dandruff compositions, to provide an improved overall anti-dandruff efficacy (see Cardin et al., col.1, L.38-45). Such a composition is stable, safe and effective in cleaning hair while simultaneously treating the scalp. Therefore, ample motivation is provided by the prior art to demonstrate the obviousness of employing routinely used ingredients, such as zinc pyridinethione, in hair and scalp formulations.

Applicant’s argument that the ‘combination of a cationic polymer with a non-volatile conditioning agent is not disclosed nor are cationic agents listed in the examples’ is not persuasive because Ramachandran *et al.* clearly teach the inclusion of these ingredients in the formulation. The teachings of the art are not limited to the examples disclosed therein since the art does recognize and teach various cationic polymers and also teach conditioning agents. Merely that the art teach the above-named ingredients in shampoo compositions is sufficient.

Secondly, Applicant argued, “Cardin solely teaches that the shampoo’s antidandruff efficacy is enhanced and there’s no teaching that the conditioning efficacy is enhanced. There is no teaching in Cardin of cationic polymers.”

These arguments were not found persuasive. It is not deemed necessary that the prior art teach each and every property attributable to a particular ingredient, merely that the prior art suggest that particular ingredient in a similar field of endeavor is sufficient. Regarding the inclusion of cationic polymers, the Examiner notes, that Cardin *et al.* was relied upon solely for the teaching of platelet particle forms of zinc pyridinethione, an anti-dandruff particulate, and was not relied upon for teaching enhanced conditioning effects, as initially this requirement was met by the primary reference of Ramachandran *et al.*

Regarding the Declaration under 37 CFR §1.132, Applicants state that “Formula A, which represents the instant invention, meets the criteria for bioavailability/coverage index and second conditioning index, whereas, Formulas B and C do not meet the criteria for bioavailability/coverage and second conditioning indexes”.

The Declaration has been reviewed but was not found persuasive. Although the art does not explicitly teach the instant bioavailability/coverage index and second conditioning index amounts, these amounts were not viewed as being critical, since Applicants have not demonstrated that the prior art would not achieve effective conditioning results using the ingredients taught in the art. Ramachandran *et al.*, for example, teach at page 10, lines 34-38, that along with conditioning agents, suspending agents are also provided to impart *improved hair conditioning effects*. The art clearly desires the objective of improving hair feel, based on the formulations suggested. Moreover, it appears that the differences of conditioning benefits are differences of degree, as the prior art does teach ‘improved hair conditioning effects’. With respect to Applicant’s invitation to submit new declarations based on Formula B and one having

quantitative values, the Examiner expresses appreciation in the Applicant's invitation, but will decline at this time for further submission of declarations for clarifying purposes.

Lastly, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ramachandran *et al.* teach a shampoo composition comprising all of the instant ingredients of generic claim 1. Ramachandran *et al.* do not explicitly teach that the zinc salt of 1-hydroxy-2-pyridinethione is in platelet particle form, as claimed in claim 17. Cardin *et al.* is relied upon to remedy this deficiency by teaching antidandruff shampoos comprising an anti-dandruff active being 1-hydroxy-2-pyridinethione salt in platelet particle form. Therefore, ample motivation is provided by the prior art since Ramachandran *et al.* teach shampoo compositions comprising conditioning agents, anti-dandruff agents, surfactants, cationic polymers and suspending agents contained in similar or overlapping amounts as instantly claimed. Cardin *et al.* further demonstrates that it is well-known to employ zinc pyridinethione salts in platelet particle form in hair formulations, specifically, anti-dandruff formulations. Both references are directed to scalp or hair formulations, employed for the cosmetic art and both references provide for aesthetically enhanced properties using the formulations taught. Thus, for these reasons, the instant invention, when taken as a whole, is rendered *prima facie* obvious over the cited art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *H.N.S.*

Patent Examiner

Art Unit 1615

December 02, 2004

James M. Spear
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